Laekna, Inc.
來凱醫藥有限公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2105)

INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED JUNE 30, 2024

The Board of Laekna, Inc. is pleased to announce the unaudited condensed consolidated interim results of the Group for the six months ended June 30, 2024, together with comparative figures for the same period of 2023, as follows.

In this announcement, "we" and "our" refer to the Company and where the context otherwise requires, the Group. Certain amounts and percentage figures included in this announcement have been subject to rounding adjustments or have been rounded to one or two decimal places. Any discrepancies in any table, chart or elsewhere between totals and sums of amounts listed therein are due to rounding issues.

BUSINESS HIGHLIGHTS

We have made significant progress with respect to the clinical and pre-clinical developments of our drug candidate assets. For the six months ended June 30, 2024, we made the following milestones and achievements:

Advancing the Clinical Trials

LAE102 in Obesity, Phase I

LAE102 is our internally discovered monoclonal antibody against ActRIIA. We submitted IND applications to both of CDE and FDA for LAE102 in obesity indication in the first quarter of 2024 and obtained approvals of the same in the second quarter of 2024. We have commenced the Phase I clinical study of LAE102 in June 2024 and ahead of our planned schedule. The Phase I clinical study is a randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics of the

therapy. We target to achieve primary completion of the single ascending dose part (the "**SAD Study**") of this Phase I clinical trial in the fourth quarter of 2024. We are committed to bringing this precision therapy to obesity patients who are in need of novel treatment options. Blocking Activin-ActRII pathway could promote muscle regeneration and decrease fat mass. Laekna team has accumulated tremendous experiences and deep knowhow in this specific field and is developing, in addition to LAE102, more drug candidates to maximize the value of targeting ActRII receptors. LAE103 is an ActRIIB-selective antibody and LAE123 is a dual inhibitor against ActRIIA/IIB. Both of them are our internally discovered antibodies for muscle and other disease indications.

LAE002 (afuresertib) +Fulvestrant in HR+/HER2-breast cancer, Phase III

The results of our Phase Ib study in this combination therapy with 20 patients from the U.S. and China have shown promising anti-cancer efficacy with a well-tolerated safety profile. The data of this study have been presented during a poster spotlight session at the 2023 San Antonio Breast Cancer Symposium (SABCS) in December 2023. We have enrolled 11 additional subjects in this Phase Ib study and further verified the promising anti-cancer efficacy with a well-tolerated safety profile indicated in the earlier stage of the study. The Group plans to present the clinical data of all enrolled patients and the patients with positive biomarker in this Phase Ib study as a poster presentation at the European Society for Medical Oncology (ESMO) Congress in Barcelona, Spain in September 2024.

The Group has commenced the Phase III clinical trial AFFIRM-205 in China for LAE002 (afuresertib, an oral AKT inhibitor) plus fulvestrant in patients with PIK3CA/AKT1/PTEN alterations and HR+/HER2- locally advanced or metastatic breast cancer ("LA/mBC") (the "**Phase III Clinical Trial AFFIRM-205**") in May 2024, which was ahead of our planned schedule. The Phase III Clinical Trial AFFIRM-205 is a multi-center, randomized, double-blind, placebo-controlled pivotal study to further assess the anti-tumor efficacy and safety of the combination therapy.

LAE002 (afuresertib) +LAE001/prednisone in mCRPC, Phase II

We initiated a Phase II multi-regional clinical trial of the study of LAE002 (afuresertib, an AKT inhibitor) plus LAE001 (CYP17A1/CYP11B2 dual inhibitor) ("**LAE201**") in patients with metastatic castration-resistant prostate cancer ("**mCRPC**") following standard of care ("**SOC**") treatment in the U.S. in June 2021, and South Korea in September 2022. The trial is an open-label, dose-escalation and dose expansion study to assess the efficacy and safety of the combination candidate. The study demonstrated promising treatment benefit for mCRPC patients. As of November 21, 2023, 40 patients who progressed on 1–3 lines of standard treatments, including at least 1 line of abiraterone, or the second generation of AR antagonists, had been enrolled in the recommended Phase II dose group. The median rPFS was 8.1 months. This is a significant improvement compared to the median rPFS of 2 to 4 months of mCRPC patients under the standard treatments historically. The combination therapy was generally tolerable with manageable treatment emergent adverse events and recoverable after routine treatments.

Design of the Phase III pivotal trial of LAE201 in patients with mCRPC following SOC treatment has been discussed with FDA. In May 2024, the Group has obtained approval from FDA for the protocol of this Phase III clinical trial. We plan to pursue strategic partnerships to accelerate the development and commercialization of LAE002 (afuresertib) and LAE001 to address the great unmet medical need for cancer therapies.

LAE002 (afuresertib) +Paclitaxel for PROC (PROFECTA-II), Phase II

We have initiated a global MRCT Phase II trial (PROFECTA-II) in both the U.S. and China to treat 150 Platinum-Resistant Ovarian Cancer ("**PROC**") patients with LAE002 (afuresertib) plus paclitaxel. Top-line data of the global MRCT Phase II trial (PROFECTA-II) was announced in January 2024. The study showed reduced risk of disease progression or death (progression-free survival; PFS) with a hazard ratio (HR) of 0.744 (95% CI: 0.502–1.102) but missed statistical significance. For biomarker subgroup with phospho-AKT positive, IHC>1, (37%), the study data demonstrated that LAE002 (afuresertib) combination arm significantly improved PFS, and the median PFS is 5.4 months vs 2.9 months with HR of 0.352 (95% CI: 0.125–0.997). We will further discuss with regulatory authorities and target to identify a registration path for PROC patient populations that may benefit from LAE002 (afuresertib).

Pre-clinical candidates (PCC) declaration

For the six months ended June 30, 2024, IND-enabling study has been initiated for LAE103 and we target to submit IND application for LAE103 (ActRIIB-selective antibody) in the second quarter of 2025. We also target to advance LAE123 (dual inhibitor against ActRIIA/IIB) to PCC declaration by the end of 2024.

Expected Upcoming Milestones

- To achieve primary completion of Single-Ascending Dose part of Phase I clinical trial of LAE102 in the fourth quarter of 2024;

- To advance LAE123 to PCC declaration by the end of 2024;

- To submit IND application for LAE120 (USP1 inhibitor) in the fourth quarter of 2024;

- To present more LAE002 (afuresertib)+fulvestrant Phase Ib clinical data and biomarker data as a poster presentation at ESMO in Barcelona, Spain in September 2024; and

- To present LAE002 (afuresertib)+Sintilimab+nab-paclitaxel Phase I clinical study results at the 2024 annual global meeting of the International Gynecologic Cancer Society ("**IGCS**") as a poster presentation in Dublin, Ireland in October 2024.

FINANCIAL HIGHLIGHTS

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Research and development expenses	**126,148**	102,337
Administrative expenses	**30,380**	35,965
Fair value changes on financial instruments issued to investors	**–**	71,210
Loss for the period	**143,706**	216,985
Total comprehensive loss for the period	**138,548**	285,759

Our research and development expenses increased by RMB23.8 million or 23.3% from RMB102.3 million for the six months ended June 30, 2023 to RMB126.1 million for the six months ended June 30, 2024. Such increase was primarily attributable to increased clinical trial milestone payment and clinical development expenses related to Phase III Clinical Trial AFFIRM-205 as first patient enrolled in May 2024.

Our administrative expenses decreased by RMB5.6 million or 15.6% from RMB36.0 million for the six months ended June 30, 2023 to RMB30.4 million for the six months ended June 30, 2024, which was primarily attributable to the decrease in listing expenses. The Company's shares were successfully listed on the Main Board of the Stock Exchange in June 2023.

Fair value changes on financial instruments issued to investors were related to preferred shares. All preferred shares were converted into ordinary shares of the Company upon completion of the Listing. Thus, no such losses were incurred during the Reporting Period.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the six months ended June 30, 2024 — unaudited

		Six months ended June 30,	
		2024	2023
	Note	***RMB'000***	*RMB'000*
Other income	*4*	**14,149**	3,243
Other losses		**(4)**	(9,928)
Administrative expenses		**(30,380)**	(35,965)
Research and development expenses		**(126,148)**	(102,337)
Loss from operations		**(142,383)**	(144,987)
Finance costs	*5(a)*	**(1,323)**	(788)
Fair value changes on financial instruments issued to investors		**–**	(71,210)
Loss before taxation	*5*	**(143,706)**	(216,985)
Income tax	*6*	**–**	–
Loss for the period		**(143,706)**	(216,985)
Other comprehensive income for the period (after tax and reclassification adjustments)			
Item that will not be reclassified to profit or loss:			
Exchange differences on translation of financial statements of the Company		**11,962**	(40,350)
Item that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of financial statements of foreign subsidiaries		**(6,804)**	(28,424)
Total comprehensive income for the period		**(138,548)**	(285,759)
Loss per share	*7*		
Basic and diluted *(RMB)*		**(0.40)**	(2.63)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

At June 30, 2024 — unaudited

	Note	**At June 30, 2024** ***RMB'000***	At December 31, 2023 *RMB'000*
Non-current assets			
Property, plant and equipment		**3,842**	4,506
Intangible assets	*8*	**123,946**	124,229
Right-of-use assets		**5,642**	6,510
Other non-current assets		**15,245**	9,009
		148,675	144,254
Current assets			
Prepayments and other receivables		**10,513**	9,114
Time deposits	*9*	**248,970**	338,120
Cash and cash equivalents	*10*	**407,331**	440,815
		666,814	788,049
Current liabilities			
Bank loans	*11*	**57,090**	49,400
Other payables	*12*	**72,484**	68,445
Lease liabilities		**2,005**	1,917
		131,579	119,762
Net current assets		**535,235**	668,287
Total assets less current liabilities		**683,910**	812,541
Non-current liabilities			
Lease liabilities		**4,189**	5,069
Deferred income		**3,500**	3,500
		7,689	8,569
NET ASSETS		**676,221**	803,972
CAPITAL AND RESERVES			
Share capital		**27**	27
Treasury shares		**(2)**	(2)
Reserves		**676,196**	803,947
TOTAL EQUITY		**676,221**	803,972

CONDENSED CONSOLIDATED CASH FLOW STATEMENT

For the six months ended June 30, 2024 — unaudited

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Operating activities		
Cash used in operations	**(143,382)**	(155,769)
Net cash used in operating activities	**(143,382)**	(155,769)
Investing activities		
Payment for purchase of property, plant and equipment	**(245)**	(101)
Proceeds from sale of property, plant and equipment	**4**	–
Payment for purchase of intangible assets	**(392)**	–
Decrease in time deposits with original maturity over three months	**89,150**	–
Interest received from bank deposits	**13,318**	2,973
Payment for purchase of wealth management products	**–**	(71,349)
Net cash generated from/(used in) investing activities	**101,835**	(68,477)
Financing activities		
Proceeds from bank loans	**42,290**	29,800
Repayment of bank loans	**(34,600)**	(9,932)
Interest paid for bank loans	**(1,167)**	(595)
Proceeds from issuance of ordinary shares through initial public offering, net of issuance costs	**–**	714,281
Payment for capital element of lease liabilities	**(792)**	(749)
Payment for interest element of lease liabilities	**(156)**	(193)
Net cash generated from financing activities	**5,575**	732,612
Net (decrease)/increase in cash and cash equivalents	**(35,972)**	508,366
Cash and cash equivalents at January 1	**440,815**	323,070
Effect of foreign exchange rate changes	**2,488**	5,710
Cash and cash equivalents at June 30	**407,331**	837,146

NOTES TO THE UNAUDITED INTERIM FINANCIAL INFORMATION

(Expressed in Renminbi unless otherwise indicated)

1 GENERAL INFORMATION

The Company was incorporated in the Cayman Islands on July 29, 2016 as an exempted company with limited liability under the law of the Cayman Islands.

The Company is an investing holding company. The Group is principally engaged in discovering, development and commercialising innovative therapies for cancer, metabolic diseases and liver fibrosis in the PRC, the U.S. and South Korea.

The Company's shares were listed on the Main Board of The Stock Exchange on June 29, 2023.

2 BASIS OF PREPARATION

This interim financial information has been prepared in accordance with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, including compliance with International Accounting Standard ("IAS") 34, *Interim financial reporting*, issued by the International Accounting Standards Board ("IASB"). It was authorised for issue on August 16, 2024.

The interim financial information has been prepared in accordance with the same accounting policies adopted in the 2023 annual financial statements, except for the accounting policy changes that are expected to be reflected in the 2024 annual financial statements. Details of any changes in accounting policies are set out in Note 3.

The preparation of an interim financial information in conformity with IAS 34 requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets and liabilities, income and expenses on a year to date basis. Actual results may differ from these estimates.

This interim financial information contains condensed consolidated financial statements and selected explanatory notes. The notes include an explanation of events and transactions that are significant to an understanding of the changes in financial position and performance of the Group since the 2023 annual financial statements. The condensed consolidated interim financial statements and notes thereon do not include all of the information required for a full set of financial statements prepared in accordance with International Financial Reporting Standards ("IFRSs").

3 CHANGES IN ACCOUNTING POLICIES

The Group has applied the following amendments to IFRSs issued by the IASB to this interim financial report for the current accounting period:

- Amendments to IAS 1, *Presentation of financial statements: Classification of liabilities as current or non-current ("2020 amendments")*
- Amendments to IAS 1, *Presentation of financial statements: Non-current liabilities with covenants ("2022 amendments")*
- Amendments to IFRS 16, *Leases: Lease liability in a sale and leaseback*
- Amendments to IAS 7, *Statement of cash flows* and IFRS 7, *Financial instruments: Disclosures — Supplier finance arrangements*

None of these developments have had a material effect on how the Group's results and financial position for the current or prior periods have been prepared or presented in this interim financial information. The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period.

4 OTHER INCOME

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Interest income from bank deposits	**13,318**	2,973
Net unrealised and realised gain on wealth management products	**–**	51
Government grants	**406**	219
Net foreign exchange gains	**425**	–
	14,149	3,243

5 LOSS BEFORE TAXATION

Loss before taxation is arrived at after charging/(crediting):

(a) Finance costs

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Interest on bank loans	**1,167**	595
Interest on lease liabilities	**156**	193
	1,323	788

(b) Staff costs

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Salaries, wages and other benefits	**43,935**	41,653
Contributions to defined contribution retirement plan	**2,580**	2,498
Equity settled share-based payment expenses	**10,797**	13,326
	57,312	57,477

(c) Other items

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Amortisation of intangible assets	**1,035**	922
Depreciation charge		
— property, plant and equipment	**708**	840
— right-of-use assets	**868**	868
	1,576	1,708
Listing expenses	**–**	10,951
Research and development expenses *(i)*	**126,148**	102,337
Net foreign exchange (gains)/losses	**(425)**	7,803

(i) During the six months ended June 30, 2024 and 2023, research and development expenses included staff costs, depreciation and amortisation expenses of RMB36,992,000 and RMB40,251,000 respectively, in which the respective amounts are also disclosed separately above.

6 INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

(i) The Cayman Islands

Pursuant to the rules and regulations of the Cayman Islands, the Company is currently not subject to income tax.

(ii) Hong Kong

The Company's subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at 16.5% of the estimated assessable profits. No provision for Hong Kong profits tax had been made for the six months ended June 30, 2024 and 2023 as there were no assessable profits.

(iii) The U.S.

The Company's subsidiary incorporated in the U.S. is subject to Federal Tax at a rate of 21% and State Profits Tax at a rate of 0.75%–9.50%. Operations in the U.S. have incurred net accumulated operating losses for income tax purposes, and no income tax provisions had been made for the six months ended June 30, 2024 and 2023.

(iv) Chinese Mainland

Pursuant to the Corporate Income Tax Law of Chinese Mainland (the "CIT"), the Company's Chinese mainland subsidiaries are subject to the CIT at a rate of 25%.

According to the new tax incentive policies promulgated by the State Tax Bureau of Chinese Mainland in March 2023, effective from January 1, 2023, an additional 100% of qualified research and development expenses incurred is allowed to be deducted from taxable income.

7 LOSS PER SHARE

The calculation of basic loss per share for the six months ended June 30, 2024 is based on the loss attributable to ordinary equity shareholders of the Company of RMB143,706,000 (six months ended June 30, 2023: RMB216,985,000) and the weighted average of 355,981,000 ordinary shares (six months ended June 30, 2023: 82,489,000 shares) in issue during the interim period.

The calculation of diluted loss per share for the six months ended June 30, 2024 and 2023 has not included the potential effects of share options issued by the Company, as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the six months ended June 30, 2024 and 2023 are the same as basic loss per share.

8 INTANGIBLE ASSETS

	In-licensed rights *RMB'000*	Software *RMB'000*	Total *RMB'000*
Cost:			
At January 1, 2024	120,711	6,602	127,313
Exchange adjustments	752	–	752
At June 30, 2024	121,463	6,602	128,065
Accumulated amortisation:			
At January 1, 2024	–	(3,084)	(3,084)
Charge for the period	–	(1,035)	(1,035)
At June 30, 2024	–	(4,119)	(4,119)
Net book value:			
At June 30, 2024	121,463	2,483	123,946
At January 1, 2024	120,711	3,518	124,229
Cost:			
At January 1, 2023	118,698	6,153	124,851
Exchange adjustments	4,451	–	4,451
At June 30, 2023	123,149	6,153	129,302
Accumulated amortisation:			
At January 1, 2023	–	(1,220)	(1,220)
Charge for the period	–	(922)	(922)
At June 30, 2023	–	(2,142)	(2,142)
Net book value:			
At June 30, 2023	123,149	4,011	127,160
At January 1, 2023	118,698	4,933	123,631

(a) In-licensed rights

The balance of in-licensed rights represents payments made to acquire development and commercialisation rights of drug products from third parties and are not ready for commercial use. Due to the inherent uncertainties in the research and development processes, these assets are particularly at risk of impairment if the projects are not expected to result in commercialised products. Key terms of these licenses are set out below:

(i) LAE001

On June 30, 2017, the Group entered into a license agreement with Novartis, pursuant to which Novartis granted the Group an exclusive license to develop, manufacture and commercialise the licensed product LAE001 world widely.

Under the terms of the agreement, the Group made an one-time and non-refundable upfront payment of USD1 million (equivalent to RMB6.6 million) and granted 776,437 ordinary shares of the Company to Novartis (equaling to 7,764,370 shares after adjusting for the effect of the share subdivision upon the Listing). The Group capitalised an amount of USD1.8 million (equivalent to RMB12.2 million) in total. The Group also agreed to make regulatory milestone payments, as well as royalty payments on net sales to Novartis.

(ii) LAE002 (afuresertib) & LAE003

On May 9, 2018, the Group entered into a license agreement with Novartis, pursuant to which Novartis granted the Group an exclusive license to develop, manufacture and commercialise the licensed products LAE002 (afuresertib) and LAE003 world widely.

Under the terms of the agreement, the Group made an one-time and non-refundable upfront payment of USD5 million (equivalent to RMB31.9 million) and granted 165,200 ordinary shares of the Company to Novartis (equaling to 1,652,000 shares after adjusting for the effect of the share subdivision upon the Listing). The Group capitalised an amount of USD5.2 million (equivalent to RMB33.5 million) in total. The Group also agreed to make clinical trial milestone payments, regulatory milestone payments, sales milestone payments, as well as royalty payments on net sales to Novartis.

(iii) LAE005

On February 4, 2020, the Group entered into a license agreement with Novartis, pursuant to which Novartis granted the Group an exclusive license to develop, manufacture and commercialise the products LAE005 world widely.

Under the terms of the agreement, the Group made an one-time and non-refundable upfront payment of USD10 million (equivalent to RMB69.4 million) to Novartis and capitalised such payment. The Group also agreed to make clinical trial milestone payments, regulatory milestone payments, sales milestone payments, as well as royalty payments on net sales to Novartis.

9 TIME DEPOSITS

As at June 30, 2024, time deposits of RMB248,970,000 (2023: RMB338,120,000) in the consolidated statement of financial position represented bank deposits with original maturity over three months.

10 CASH AND CASH EQUIVALENTS

	At June 30, 2024	At December 31, 2023
	RMB'000	*RMB'000*
Cash at banks	**290,398**	171,626
Deposits with banks	**116,933**	269,189
	407,331	440,815

As at June 30, 2024, cash and cash equivalents of the Group situated in Chinese mainland amounted to RMB377,091,000 (2023: RMB207,172,000). Remittance of funds out of Chinese mainland is subject to relevant rules and regulations of foreign exchange control.

11 BANK LOANS

	At June 30, 2024	At December 31, 2023
	RMB'000	*RMB'000*
Unsecured bank loans due within 1 year	**57,090**	49,400

As at June 30, 2024, unsecured bank loans carried interest at annual rates ranging from 3.30% to 4.10% (2023: 3.40% to 4.35%) per annum and were all repayable within one year.

12 OTHER PAYABLES

	At June 30, 2024	At December 31, 2023
	RMB'000	*RMB'000*
Payroll payables	**800**	14,279
Accrued research and development expenses	**64,634**	42,939
Other payables and accrued charges	**7,050**	11,227
	72,484	68,445

13 DIVIDENDS

The Board did not propose any dividend during the six months ended June 30, 2024 (six months ended June 30, 2023: nil).

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

We are a science-driven, clinical-stage biotechnology company committed to bringing novel therapies to patients with cancer, metabolic diseases and liver fibrosis around the world. As of June 30, 2024, we have initiated seven clinical trials for LAE102, LAE002 (afuresertib), LAE001 and LAE005 to address unmet medical need in obesity and cancers.

We have assembled a seasoned management team with extensive experience and expertise covering the full cycle of drug discovery and development process, from pre-clinical asset discovery, clinical trial design and execution to regulatory process management and drug manufacturing. As of June 30, 2024, we were supported by a talented R&D team consisting of 64 employees, with 15 holding doctorate degrees and 33 holding master's degrees. Our core management team has established a long track record of accomplishment, leadership and deep knowledge in their respective fields.

LAE102 is our internally discovered antibody against ActRIIA. It has been shown in the pre-clinical studies to be a potential drug candidate developed for obesity indication to increase lean mass and decrease fat mass. We submitted IND applications to both of CDE and FDA in obesity indication in the first quarter of 2024 and obtained approvals of the same in the second quarter of 2024. We have commenced the Phase I clinical study of LAE102 and dosed the first subject in June 2024, which was ahead of our planned schedule. We target to achieve primary completion of the SAD part of this Phase I clinical trial in the fourth quarter of 2024. We are committed to bringing this precision therapy to obesity patients who are in need of novel treatment options. Laekna has been pursuing strategic partnerships to accelerate the development and commercialization of LAE102 for such important indications with a great unmet medical need.

Blocking Activin-ActRII pathway could promote muscle regeneration and decrease fat mass. Laekna team has accumulated tremendous experiences and deep knowhow in this specific field and is developing more drug candidates to maximize the value of targeting ActRII receptors. LAE103 is an ActRIIB-selective antibody and LAE123 is a dual inhibitor against ActRIIA/IIB. Both of them are our internally discovered antibodies for muscle and other disease indications.

In the cancer area, we have built a comprehensive portfolio of drug candidates, including LAE002 (afuresertib), LAE001 and other eight drug candidates. LAE002 (afuresertib) is a potent AKT inhibitor that inhibits all three AKT isoforms (AKT1, AKT2 and AKT3) as well as one of the two AKT inhibitors in late-stage development for breast and prostate cancer globally. LAE002 (afuresertib) has demonstrated several superior features compared to other AKT inhibitors, including higher efficacy, better potency, more significant tumor inhibition exposure and a better safety profile, based on the public data. Capivasertib is the first approved AKT inhibitor from AstraZeneca, which FDA approved for HR+/HER2- breast cancer in November 2023. With the promising efficacy data from our LAE002 (afuresertib) Phase Ib study for HR+/HER2- breast cancer, the Group has initiated the Phase III pivotal study. First patient was enrolled in May 2024 and was ahead of our planned schedule. The Group plans to bring this precision therapy to HR+/HER2- LA/mBC patients who are in need of novel treatment options.

We also continue to develop our clinical trials for the treatment of breast cancer, prostate cancer, ovarian cancer and PD-1/PD-L1 drug-resistant solid tumors to address the unmet medical need. In several clinical trials, the combination of LAE002 (afuresertib) with other therapeutics exhibits favorable efficacy results.

MARKET OPPORTUNITIES IN OBESITY AND CANCER TREATMENTS

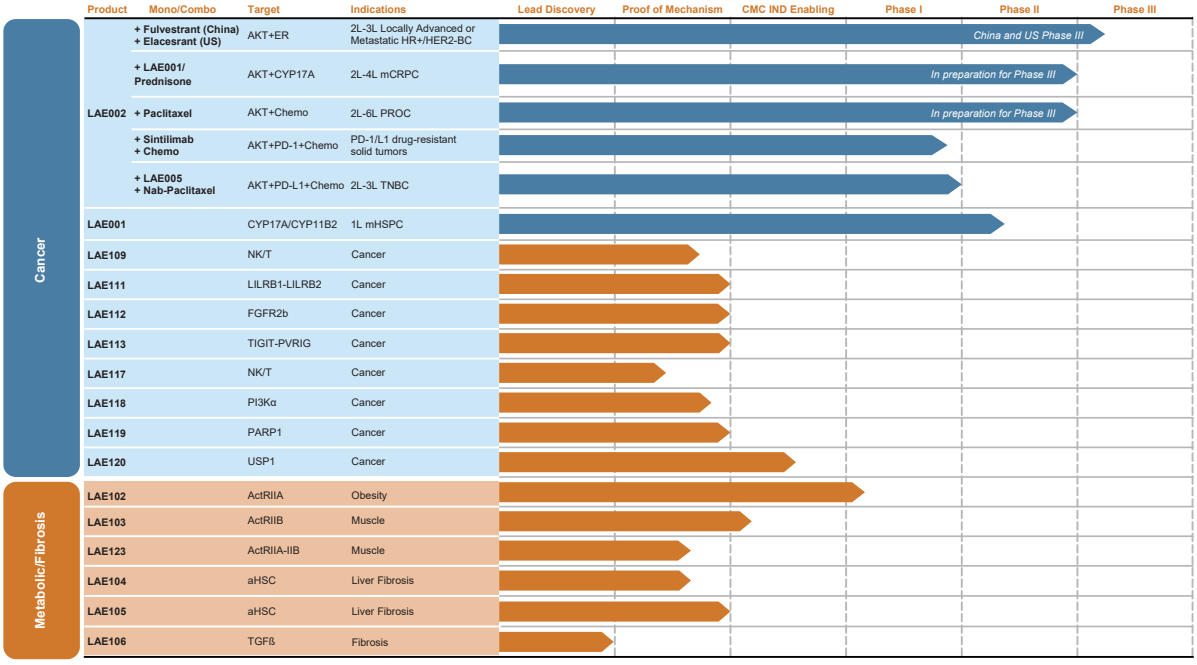
Globally, the number of people living with obesity is set to reach over 1.2 billion by 2030[1]. The causes of obesity are complex and, so often, it puts people on a path to other diseases — not only diabetes, but also heart and liver diseases, cancers and many more. There are growing understandings of the critical need to treat obesity among both the medical community and the public, while an increasing number of people living with such disease are actively seeking support.

Although the field of cancer treatment has progressed significantly in the past decade, a large proportion of cancer patients find themselves in the absence of effective or safe treatments. The quality of life of those patients is severely affected, primarily attributable to SOC treatment resistance and/or intolerable toxicity, resulting in a large unmet medical need and a socioeconomic burden. Among those cancers of unmet medical need, HR+/HER2- metastatic breast cancer (HR+/HER2- mBC), mCRPC, PROC and triple negative breast cancer (TNBC) are some of the diseases with limited SOC options and unsatisfactory treatment outcomes.

[1] (World Obesity Federation, 2023b)

PIPELINE

The following chart summarizes the development status of our clinical-stage drug candidates and selected pre-clinical-stage drug candidates as of the date of this announcement:



BUSINESS REVIEW

During the six months ended June 30, 2024, the Company has made significant progress with respect to its drug pipeline and business operations, including the following milestones and achievements.

LAE102

LAE102 is our internally discovered ActRIIA-specific monoclonal antibody. It has been shown in the pre-clinical studies to be a potential drug candidate developed for obesity indication to increase lean mass and decrease fat mass. We submitted IND applications to CDE and FDA for obesity indication in the first quarter of 2024 and obtained approval of the same in the second quarter of 2024. The Group has commenced study recruitment in Phase I clinical trial of LAE102 in China and the first subject was dosed in June 2024, which was ahead of our planned schedule. The Phase I clinical trial of LAE102 is a randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics of the therapy. We target to achieve primary completion of the SAD part of this Phase I clinical trial in the fourth quarter of 2024. The Group targets to bring this precision therapy to overweight and obesity patients who are in need of novel treatment options for achieving quality weight control.

Blocking Activin-ActRII pathway could promote muscle regeneration and decrease fat mass. Laekna team has accumulated tremendous experiences and deep knowhow in this specific field and is developing more drug candidates to maximize the value of targeting ActRII pathway. LAE103 is an ActRIIB- selective antibody and LAE123 is a dual inhibitor against ActRIIA/IIB. Both of them are our internally discovered antibodies for muscle and other disease indications in our pipeline of drug candidates.

Laekna has been pursuing strategic partnerships to accelerate the development and commercialization of LAE102 for such important indication with a great unmet medical need outside of the cancer therapeutic area.

LAE002 (afuresertib)

LAE002 (afuresertib) is an adenosine triphosphate (ATP) competitive AKT inhibitor. We in-licensed LAE002 (afuresertib) from Novartis in 2018. Prior to our in-licensing, 11 clinical trials had been conducted to demonstrate the safety and efficacy profiles of LAE002 (afuresertib) by Novartis and GSK.

LAE002 (afuresertib) +Fulvestrant in HR+/HER2-breast cancer

According to Frost & Sullivan, the global and China's incidence of breast cancer is expected to increase from 2,301.2 thousand and 336.3 thousand in 2021 to 2,666.4 thousand and 372.4 thousand in 2030, respectively. It is estimated that more than 60% of patients with breast cancer have HR+/HER2- molecular signature in China. The endocrine/anti-estrogen therapies in combination with CDK4/6 inhibitors have emerged as the first- and/or the second-line treatment for patients with HR+/HER2- breast cancer. However, 15% to 20% of patients are intrinsically resistant to the treatment, and another 30% to 40% patients will develop acquired resistance to the treatment over time. HR+/HER2-breast cancer post CDK4/6 inhibitors and endocrine treatments remain as a huge unmet medical need and represent a multi-billion dollar market potential.

We have initiated a Phase Ib trial in China and the U.S. for the treatment of HR+/HER2-LA/mBC with LAE002 (afuresertib), in a combination of a SOC treatment fulvestrant. The results of our Phase Ib study in this combination therapy with 20 patients from the U.S. and China have shown promising anti-cancer efficacy with a well-tolerated safety profile. The data of this study have been presented during a poster spotlight session at the 2023 San Antonio Breast Cancer Symposium (SABCS) in December 2023. We have enrolled 11 additional subjects in this Phase Ib study and further verified the promising anti-cancer efficacy with a well-tolerated safety profile indicated in the earlier stage of the study. The Group plans to present the clinical data of all enrolled patients and the patients with positive biomarker in this Phase Ib study as a poster presentation at ESMO in Barcelona, Spain in September 2024.

The Group has commenced the Phase III Clinical Trial AFFIRM-205 in China for LAE002 (afuresertib, an oral AKT inhibitor) plus fulvestrant in patients with PIK3CA/AKT1/PTEN alterations and HR+/HER2-LA/mBC in May 2024, which was ahead of our planned schedule. The Phase III Clinical Trial AFFIRM-205 is a multi-center, randomized, double-blind, placebo-controlled pivotal study to further assess the anti-tumor efficacy and safety of the combination therapy.

LAE002 (afuresertib) +LAE001/prednisone in mCRPC

According to Frost & Sullivan, the global and China's incidence of prostate cancer is expected to increase from 1,451.5 thousand and 120.9 thousand in 2021 to 1,815.1 thousand and 199.3 thousand in 2030, respectively. Patients with prostate cancer that have relapsed after local therapy or that have distant metastasis usually respond to androgen deprivation therapy (ADT). However, despite receiving ADT, most of these patients eventually experience disease progression and develop castration-resistant prostate cancer (CRPC).

We initiated a Phase II multi-regional clinical trial of the study of LAE201 in patients with mCRPC following SOC treatment in the U.S. in June 2021, and South Korea in September 2022. The trial is an open-label, dose-escalation and dose expansion study to assess the efficacy and safety of the combination candidate. The study demonstrated promising treatment benefit for mCRPC patients. As of November 21, 2023, 40 patients who progressed on 1-3 lines of standard treatments, including at least 1 line of abiraterone, or the second generation of AR antagonists, had been enrolled in the recommended Phase II dose group. The median rPFS was 8.1 months. This is a significant improvement compared to the median rPFS of 2 to 4 months of mCRPC patients under the standard treatments historically. The combination therapy was generally tolerable with manageable treatment emergent adverse events and recoverable after routine treatments.

Design of the Phase III pivotal trial of LAE201 in patients with mCRPC following SOC treatment has been discussed with FDA. In May 2024, the Group has obtained approval from FDA for the protocol of this Phase III clinical trial. We plan to pursue strategic partnerships to accelerate the development and commercialization of LAE002 (afuresertib) and LAE001 to address the great unmet medical need for cancer therapies.

LAE002 (afuresertib) +Paclitaxel for PROC (PROFECTA-II)

PROC is broadly defined as ovarian cancer recurrence within six months of completing platinum-based chemotherapy, either in the primary or recurrent setting. PROC is generally associated with low response rates to standard chemotherapy with the ORR of 10% to 15%, and median PFS of 3.5 months only, indicating limited effective treatment options and poor prognosis. Treatment options are limited for PROC. According to Frost & Sullivan, the global and China's incidence of ovarian cancer is expected to increase from 319.8 thousand and 56.2 thousand in 2021 to 374.2 thousand and 62.7 thousand in 2030, respectively.

We have initiated a global MRCT Phase II trial (PROFECTA-II) in both the U.S. and China to treat PROC patients with LAE002 (afuresertib) plus paclitaxel. It was a Phase II, randomized, open-label, active-controlled study evaluating the efficacy and safety of LAE002 (afuresertib) in combination with paclitaxel versus paclitaxel in 150 patients with PROC. In January 2024, we had achieved database lock and announced the top-line data. The study showed reduced risk of disease progression or death (progression-free survival; PFS) with a HR of 0.744 (95% CI: 0.502–1.102) but missed statistical significance. For biomarker subgroup with phospho-AKT positive, IHC>1, (37%), the study data demonstrated that LAE002 (afuresertib) combination arm significantly improved PFS, and the median PFS is 5.4 months vs 2.9 months with HR of 0.352 (95% CI: 0.125–0.997). The trial has shown a manageable and tolerable safety profile and adverse events were consistent with the known safety profiles of the individual treatments. The Group will further discuss with regulatory authorities and target to identify a registration path for PROC patient populations that may benefit from LAE002 (afuresertib).

In addition, we are actively conducting other clinical trials to further expand the indications of LAE002 (afuresertib) in other cancers. We are collaborating with Innovent Biologics (Suzhou) Co. Ltd. in a combination therapy with sintilimab targeting patients with solid tumors progressed upon prior PD-1/PD-L1 treatments and/or chemotherapy. We have observed high response rate in cervical and endometrial cancer patients who have been treated up to 3 lines of SOCs, including PD-1 drugs and/or chemotherapy. We plan to present LAE002 (afuresertib)+Sintilimab+nab-paclitaxel Phase I clinical study results at the 2024 annual global meeting of the ICGs as an poster presentation in Dublin, Ireland in October 2024.

LAE001

LAE001 is an androgen synthesis inhibitor that inhibits both CYP17A1 and CYP11B2. We in-licensed LAE001 from Novartis in 2017. According to Frost & Sullivan, LAE001 is the only dual CYP17A1/CYP11B2 inhibitor in clinical trials for the treatment of prostate cancer globally. As a dual CYP17A1/CYP11B2 inhibitor, LAE001 can block both androgen and aldosterone synthesis and potentially be administrated without prednisone, the short-term high dose or long-term exposure of which can lead to a variety of adverse events.

We completed a Phase I clinical trial of LAE001 as a monotherapy and a Phase II clinical trial of LAE001 plus LAE002 (afuresertib) in patients with mCRPC to assess the safety and efficacy of the therapies. Design of the Phase III pivotal trial of LAE201 in patients with mCRPC following SOC treatment has been discussed with FDA and approval of the same has been obtained in May 2024. We plan to pursue strategic partnerships to accelerate the development and commercialization of LAE001 to address the unmet medical need for cancer therapies.

LAE005

LAE005 is a high-affinity, ligand-blocking, humanized anti-PD-L1 IgG4 antibody. In the pre-clinical and clinical studies, LAE005 demonstrated its strong binding avidity to PD-L1 and compelling anti-tumor activities. Specifically, we are evaluating the therapeutic potential of the combination therapy of LAE002 (afuresertib) and LAE005 in patients with TNBC. We believe LAE005 has the potential to serve as an effective therapy for the treatment of TNBC when combined with other synergistic mechanisms.

The results of our Phase I trial of the AKT inhibitor LAE002 (afuresertib) in combination with LAE005 (anti-PDL1 mAb) plus nab-paclitaxel for the treatment of triple-negative breast cancer (TNBC) were presented at the 2024 Annual Meeting of the American Association for Cancer Research (AACR) in April 2024. A total of 22 patients with advanced solid tumors were enrolled and dosed in this Phase I study, among which there were 14 TNBC patients who completed at least 2 cycles of treatment and had at least 1 tumor assessment. The median value of previous treatment lines of these 14 patients was 1.5 (0-3). Among the 14 TNBC patients who completed at least 2 cycles of treatment and had at least 1 tumor assessment, five showed confirmed partial response (ORR 35.7%), four had stable disease (28.6%), resulting in a disease control rate (DCR) of 64.3% in the best response assessment. The median duration of response (DOR) was 9.26 months. Five TNBC patients were treated for more than 32 weeks, with one patient reaching a duration of 73 weeks. This case study has been selected for the "Chinese Clinical Case Achievement Database" (with the PFS of this case being 16 months as of September 28, 2023).

CAUTIONARY STATEMENT: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP OR MARKET THE RELEVANT PRODUCTS, OR ANY OF OUR PIPELINE PRODUCTS, SUCCESSFULLY.

FINANCIAL REVIEW

The following discussion is based on, and should be read in conjunction with, the financial information and notes included elsewhere in this announcement.

Other Income

Our other income increased by RMB10.9 million or 340.6% from RMB3.2 million for the six months ended June 30, 2023 to RMB14.1 million for the six months ended June 30, 2024, which was primarily attributable to the increase in interest income from bank deposits for the six months ended June 30, 2024.

Other Losses

Our other losses decreased by RMB9.9 million or 100.0% from RMB9.9 million for the six months ended June 30, 2023 to RMB4,000 for the six months ended June 30, 2024, which was primarily attributable to the decrease in net foreign exchange losses.

Administrative Expenses

Our administrative expenses decreased by RMB5.6 million or 15.6% from RMB36.0 million for the six months ended June 30, 2023 to RMB30.4 million for the six months ended June 30, 2024. Such decrease was primarily attributable to the decrease in listing expenses as the Company's shares were successfully listed on the Stock Exchange in June 2023.

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
	Unaudited	Unaudited
Staff costs	**22,732**	19,642
Professional service expenses	**4,609**	3,135
Listing expenses	**–**	10,951
Others	**3,039**	2,237
Total	**30,380**	35,965

Research and Development Expenses

Our research and development expenses increased by RMB23.8 million or 23.3% from RMB102.3 million for the six months ended June 30, 2023 to RMB126.1 million for the six months ended June 30, 2024. Such increase was primarily attributable to increased clinical trial milestone payment and clinical development expenses related to Phase III Clinical Trial AFFIRM-205 as first patient enrolled in May 2024.

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
	Unaudited	Unaudited
Staff costs	**34,580**	37,835
Discovery research expenses	**13,140**	11,214
Clinical development expenses	**54,417**	49,040
Clinical trial milestone payment	**17,758**	–
Others	**6,253**	4,248
Total	**126,148**	102,337

Fair Value Changes on Financial Instruments Issued to Investors

Our fair value changes on financial instruments issued to investors decreased from RMB71.2 million for the six months ended June 30, 2023 to nil for the six months ended June 30, 2024. Fair value changes on financial instruments issued to investors were related to preferred shares. All preferred shares were converted into ordinary shares of the Company upon the completion of the Listing. Thus, no such losses were incurred during the Reporting Period.

Liquidity and Financial Resource

As of June 30, 2024, the current assets of the Group were RMB666.8 million, including cash and cash equivalents of RMB407.3 million, time deposits with an original maturity over three months of RMB249.0 million and other current assets of RMB10.5 million. Among them, the Group's cash and cash equivalents decreased by RMB33.5 million or 7.6% to RMB407.3 million as of June 30, 2024 from RMB440.8 million as of December 31, 2023. The Group's time deposits decreased by RMB89.1 million or 26.4% to RMB249.0 million as of June 30, 2024 from RMB338.1 million as of December 31, 2023. As of June 30, 2024, the current liabilities of the Group were RMB131.6 million, including other payables of RMB72.5 million, interest-bearing bank loans of RMB57.1 million and current lease liabilities of RMB2.0 million.

Our cash and bank balances (including cash and cash equivalents and time deposits) as of June 30, 2024 were RMB656.3 million, of which RMB22.8 million, RMB611.7 million and RMB21.8 million were denominated in RMB, USD, and HKD, respectively representing a decrease of 15.7% as compared to the cash and bank balances (including cash and cash equivalents and time deposits) of RMB778.9 million as of December 31, 2023. The decrease was primarily attributable to the net cash used in operating activities.

Funding and Treasury Policy

The Group adopts a prudent funding and treasury policy, aiming to maintain an optimal financial position and minimal financial risks. We have formulated internal control measures to control our process of investment in wealth management products. Prior to making an investment, we ensure that there remains sufficient working capital for our operations, R&D activities and capital expenditures. For the six months ended June 30, 2024, we funded our operations primarily through equity financing and bank loans. With the continuing expansion of our business and development of new drug candidates, we will use the net proceeds raised from the Global Offering and may require further funding through public or private equity offerings, debt financing and other sources.

Bank Loans

Our bank loans as of June 30, 2024 were RMB57.1 million (December 31, 2023: RMB49.4 million), all of which were denominated in RMB and carried fixed nominal interest rates ranging from 3.30% to 4.10% per annum.

Current ratio

Current ratio (calculated by current assets divided by current liabilities) of the Group as of June 30, 2024, was 5.07 (December 31, 2023: 6.58).

Gearing ratio

Gearing ratio is calculated by using interest-bearing borrowings and lease liabilities less cash and cash equivalents, divided by total equity and multiplied by 100%. As of June 30, 2024, the Group was in a net cash position and thus, gearing ratio is not applicable.

Foreign Currency Risk

We have transactional currency exposures. Certain of our cash and bank balances, time deposits, prepayments, other receivables and other payables are denominated in non-functional currencies and exposed to foreign currency risk. We currently do not have a foreign currency hedging policy. However, the management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

Contingent Liabilities

As of June 30, 2024, we did not have any material contingent liabilities.

Significant Investments Held

As of June 30, 2024, the Group did not hold any significant investments. Save as disclosed in this announcement, as of June 30, 2024, the Group did not have future plans for material investments and capital assets.

Pledge of Assets

As of June 30, 2024, we did not pledge any of our assets.

Employees and Remuneration Policies

As of June 30, 2024, the Group had 92 employees. The total employee benefit expenses for the six months ended June 30, 2024, including share-based payment expenses, were RMB57.3 million, as compared to RMB57.5 million for the six months ended June 30, 2023.

Our employees' remuneration comprises salaries, bonuses, provident funds, social security contributions and other welfare payments. We have made contributions to our employees' social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds pursuant to applicable laws and regulations.

We adopted the Post-IPO Share Option Scheme on June 9, 2023, which was immediately prior to Listing. We further adopted the 2024 Share Award Scheme on June 14, 2024. Each of the schemes constitutes a share scheme governed by Chapter 17 of the Listing Rules.

Material Acquisitions and Disposals

During the Reporting Period, the Group did not have any material acquisition or disposal of its subsidiaries, associates and joint ventures.

Use of Net Proceeds from the Global Offering

On June 29, 2023, 63,728,000 shares of US$0.00001 each were issued at a price of HK$12.41 per share in connection with the Company's listing on the Main Board of the Stock Exchange. The net proceeds of HK$724.4 million from the Global Offering, were used during the Reporting Period, and the unutilized net proceeds are intended to be used, according to the intentions as previously set out in the Prospectus.

The below table sets out the proposed and actual applications of the net proceeds from the Listing Date to June 30, 2024.

Intended use of Net Proceeds	**Net Proceeds from the Global Offering** *(HK$ million)*	**Approximate % of total Net Proceeds**	**Unutilized Net Proceeds from the Global Offering as of January 1, 2024** *(HK$ million)*	**Utilized Net Proceeds during the six months ended June 30, 2024** *(HK$ million)*	**Utilized Net Proceeds from the Global Offering as of June 30, 2024** *(HK$ million)*	**Unutilized Net Proceeds from the Global Offering as of June 30, 2024** *(HK$ million)*	**Expected timeline of full utilization of the unutilized Net Proceeds**[(1)]
For rapidly advancing the clinical development and approval of our Core Products, i.e. LAE001 and LAE002 (afuresertib)	407.8	56.3%	337.6	76.6	146.8	261.0	Before December 31, 2025
For accelerating the research and development of other existing pipeline products and continuously advancing and improving our pipeline products	150.7	20.8%	119.6	44.3	75.4	75.3	Before December 31, 2025
For improving our production capabilities and developing our manufacturing capacities	71.7	9.9%	71.2	4.4	4.9	66.8	Before December 31, 2025
For business development activities and enhancing our global reach	55.1	7.6%	48.3	7.4	14.2	40.9	Before December 31, 2025
For working capital and other general corporate purposes	39.1	5.4%	14.6	14.6	39.1	–	

Note:

(1) The expected timeline is based on the best estimation made by the Group on future market condition and may change with the future market condition and future development.

FUTURE DEVELOPMENT

We will continue to build our product portfolio and advance the development of our existing drug candidates towards commercialization by continuously executing innovative and tailored clinical trial designs for each of our drug candidates and strengthening our relationships with key external parties, including PIs, KOLs, CROs, SMOs, CDMOs, hospitals and others. We expect to achieve and deliver major development milestones for our drug candidates, including LAE102, LAE002 (afuresertib), LAE001, LAE005 and LAE003, to further explore their therapeutic potential.

We will continue to actively explore potential combination therapy opportunities among our pipeline and with existing approved drugs as well as conventional therapies. Our experience in executing and developing combination therapies among our pipeline, such as LAE002 (afuresertib) and LAE001, to treat the second-generation A/AR drug-resistant mCRPC has well demonstrated our ability to unleash the clinical value of our pipeline products. Our LAE002 (afuresertib) combination trial with Fulvestrant has demonstrated great clinical value to treat HR+/HER2- breast cancer patients who have failed previous standard care treatments of endocrine/anti-estrogen therapies, including CDK4/6 inhibitors which represent a big unmet medical need with huge market potential.

Finally, we hope to expand our drug pipeline through our in-house discovery to address a high unmet medical need of broader underserved patients. We are developing multiple innovative drug candidates, including small molecules, bispecific antibodies, and bifunctional NK engagers against cancer cells, activated hepatic stellate cells as well as obesity and metabolic diseases. LAE102 is our internally discovered antibody against ActRIIA. It has been shown in the pre-clinical studies to be a potential drug candidate developed for obesity indication to increase lean mass and decrease fat mass. We submitted IND applications to CDE and FDA respectively in relation to obesity indication in the first quarter of 2024 and obtained the IND approval from FDA and CDE in the second quarter of 2024 respectively. We have commenced clinical trial process after obtaining IND approval and are committed to bringing this precision therapy to obesity patients who are in need of novel treatment options. Blocking Activin-ActRII pathway could promote muscle regeneration and decrease fat mass. LAE103 is an ActRIIB-selective antibody and LAE123 is a dual inhibitor for ActRIIA/IIB. Both of them are our internally discovered antibodies for muscle regeneration indications in the drug candidate pipeline. Our innovative drug candidates are in various stages of drug discovery and development, and we plan to have one drug candidate entering the clinical stage each year.

CORPORATE GOVERNANCE RELATED INFORMATION

Compliance with Corporate Governance Code

The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the Shareholders as a whole. The Company has adopted the CG Code contained in Appendix C1 to the Listing Rules as its own code of corporate governance. The Directors are of the view that during the Reporting Period, the Company has complied with all applicable code provisions of the CG Code save and except for the following deviation from code provision C.2.1 of the CG Code.

Under code provision C.2.1 of the CG Code, the roles of chairman and chief executive should be separate and should not be performed by the same individual. Dr. LU Chris Xiangyang ("**Dr. Lu**") has served as our chairman since May 2018 and chief executive officer since April 2017. Dr. Lu is the founder of our Group and has extensive experience in the business operations and management of our Group. Our Board believes that, in view of his experience, personal profile and his roles in our Company as mentioned, Dr. Lu is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our chief executive officer. Our Board also believes that the combined role of chairman and chief executive officer can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board. Our Directors consider that the balance of power and authority will not be impaired due to this arrangement. In addition, all major decisions are made in consultation with members of the Board, including the relevant Board committees, and three independent non-executive Directors.

The Board will continue to review the effectiveness of the corporate governance structure of the Group in order to assess whether separation of the roles of chairman and the chief executive officer is necessary.

Compliance with the Model Code for Securities Transactions

The Company has adopted the Model Code as its own code of conduct regarding dealings in the securities of the Company by the Directors and the Company's senior management who, because of his/her office or employment, is likely to possess inside information in relation to the Company or its securities.

Upon specific enquiry, all Directors confirmed that they have complied with the Model Code during the Reporting Period. In addition, the Company is not aware of any non-compliance of the Model Code by the employees of the Company who are likely to be in possession of inside information of the Company during the Reporting Period.

PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S LISTED SECURITIES

Neither the Company nor any of its subsidiaries purchased, redeemed or sold any of the Company's listed securities (including sale of treasury shares) during the Reporting Period.

AUDIT COMMITTEE AND REVIEW OF INTERIM RESULTS

The Company has established an Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and the CG Code. The primary duties of the Audit Committee are to assist the Board by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of the Group, overseeing the audit process and performing other duties and responsibilities as assigned by the Board. The Audit Committee currently consists of two independent non-executive Directors being Mr. ZHOU Jian and Dr. LI Min, and one non-executive Director being Dr. WANG David Guowei. The chairperson of the Audit Committee is Mr. ZHOU Jian. Mr. ZHOU Jian holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing rules.

The Audit Committee had reviewed, together with the management, the accounting principles and policies adopted by the Group and discussed internal controls and financial reporting matters including a review of the unaudited interim financial information of the Group for the Reporting Period.

In addition, the Company's independent auditor, KPMG, has performed an independent review of the Group's interim financial information for the Reporting Period in accordance with Hong Kong Standard on Review Engagements 2410 "*Review of interim financial information performed by the independent auditor of the entity*" issued by the Hong Kong Institute of Certified Public Accountants.

EVENTS AFTER THE REPORTING PERIOD

Save as disclosed in this announcement and as at the date of this announcement, there were no material subsequent events after the Reporting Period.

INTERIM DIVIDEND

The Board does not declare the payment of an interim dividend to the Shareholders for the Reporting Period.

PUBLICATION OF RESULTS ANNOUNCEMENT AND INTERIM REPORT

This announcement is published on the website of the Stock Exchange at www.hkexnews.hk and on the website of the Company at www.laekna.com. The interim report of the Company for the six months ended June 30, 2024 containing all the information required by the Listing Rules will be published on the same websites and dispatched (if requested) to the Shareholders in due course.

DEFINITIONS

In this announcement, unless the context otherwise requires, the following expressions shall have the following respective meanings:

"AE"	adverse events, any untoward medical occurrences in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
"AKT"	a serine/threonine protein kinase with 3 isoforms (AKT1, AKT2 and AKT3) that participate in multiple pathways regulating several cellular processes, including survival, proliferation, tissue invasion, and metabolism
"Audit Committee"	the audit committee of the Board
"Board"	the board of directors of our Company
"CDE"	the center for drug evaluation of the NMPA
"CG Code"	the Corporate Governance Code as set out in Appendix C1 to the Listing Rules
"China" or "PRC"	the People's Republic of China, but for the purpose of this announcement and for geographical reference only and except where the context requires otherwise, references in this announcement to "China" and the "PRC" do not apply to Hong Kong, Macau Special Administrative Region of the People's Republic of China and Taiwan
"CMC"	chemistry, manufacture and control

"Company" or "Our Company"	Laekna, Inc. (來凱醫藥有限公司), an exempted company incorporated in the Cayman Islands with limited liability on July 29, 2016
"Director(s)" or "our Director(s)"	the directors of the Company
"FDA"	the United States Food and Drug Administration
"Global Offering"	the Hong Kong Public Offering and the International Offering
"Group", "our Group", "we", "us" or "our"	our Company and its subsidiaries
"HK$" or "HKD"	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
"Hong Kong"	the Hong Kong Special Administrative Region of the People's Republic of China
"HR+/HER2-breast cancer"	the most common type of breast cancer with overexpression of HR and without overexpression of HER2
"IHC"	immunohistochemistry, a test that uses a chemical dye to stain and measure specific proteins
"IND"	investigational new drug, the application for which is the first step in the drug review process by regulatory authorities to decide whether to permit clinical trials; also known as clinical trial application, or CTA, in China
"Listing"	the listing of the Shares on the Main Board of the Stock Exchange
"Listing Date"	June 29, 2023
"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended or supplemented from time to time
"mCRPC"	metastatic castration resistant prostate cancer

"Model Code"	the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix C3 to the Listing Rules
"MRCT"	multi-regional clinical trials
"NDA"	new drug application
"NMPA"	the National Medical Products Administration (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)
"Novartis"	Novartis Pharma AG, a company organized under the laws of Switzerland and one of our Pre-IPO Investors
"PCC"	pre-clinical candidate
"PD-1"	programmed cell death protein 1
"PFS"	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives without the disease getting worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works
"PROC"	platinum resistant ovarian cancer
"Prospectus"	the prospectus of the Company dated June 16, 2023
"Reporting Period"	the six months ended June 30, 2024
"RMB"	Renminbi, the lawful currency of China
"rPFS"	radiographic progression free survival
"RP2D"	recommended Phase II dose
"SAE"	serious AE, any medical occurrence in human drug trials that at any dose: results in death; is life- threatening; requires inpatient hospitalization or causes prolongation of existing hospitalization; results in persistent or significant disability/incapacity; may have caused a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage

"Share(s)"	ordinary share(s) in the share capital of our Company with a par value of US$0.00001 each
"Shareholder(s)"	holder(s) of Shares
"SOC"	treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals
"South Korea"	the Republic of Korea
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"TEAE"	adverse events not present prior to medical treatment, or an already present event that worsens either in intensity or frequency following the treatment
"TNBC"	triple-negative breast cancer, any breast cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2
"United States" or "U.S."	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"US$" or "USD"	United States dollars, the lawful currency of the United States
"%"	per cent

By order of the Board
Laekna, Inc.
Dr. LU Chris Xiangyang
Chairman

Hong Kong, August 16, 2024

As at the date of this announcement, the Board comprises Dr. LU Chris Xiangyang, Ms. XIE Ling and Dr. GU Xiang-Ju Justin as executive Directors; Dr. WANG David Guowei and Mr. SUN Yuan as non-executive Directors; and Dr. YIN Xudong, Dr. LI Min and Mr. ZHOU Jian as independent non-executive Directors.